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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,920	02/01/2000	ARNE EEK	1103326-0603	6956

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/463,920	Eek et al.
Examiner	**Art Unit**
Susan Tran	1615

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 29, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32 and 35-39* is/are pending in the application.

4a) Of the above, claim(s) *28-30, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-27, 31, 32, 35, 38, and 39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Prior Art filed 02/01/00, Change of Power Attorney filed 11/08/00, Preliminary Amendment A filed 02/02/02, Election filed 04/29/02, and Letter filed 05/13/02.

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. Claims 2-27, 31, and 32 are, either directly or indirectly depend on claim 1, which are now subjected to being rejoined. Claim 35 is also subjected to being rejoined.

Claims 28-30, and 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 8.

Requirement for restriction practice are set forth in MPEP§803.

There are two criteria for a proper requirement for restriction between patentable distinct inventions:

1. The inventions must be distinct as claimed (see MPEP§806.05-806.05(I)); and

2. There must be a serious burden on the examiner if restriction is not required (see MPEP§803.02, 806.04(a)-(j), 808.01(a) and 808.02).

The traversal is on the grounds that a search for process claims 28-30 and product claims 36, 37 would not be a serious burden on the examiner. This is not found persuasive because method and product are statutorily distinct categories of invention, and the particular method claimed is distinct from the particular product claimed because there is an alternative method of making the device. Therefore, there is no reason why a search for the method must include a search for the device as well.

Distinctness between a process of making and the product made is shown if "the product as claimed can be made by another materially different process." MPEP§806.05(f).

A serious burden on the examiner is shown according to the criteria of MPEP§808.02, where one of the following must be supported by appropriate explanation:

1. Separate classification thereof (this shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search,. Patents need not be cited to show separate classification);

2. A separate status in the art when they are classifiable together; and

3. A different field of search.

In the restriction requirement of 03/27/02, the examiner set forth separate classification for the three inventions to which claims were presented. Classification of the process claims is in class 424. Classification of the composition of Group V claim is in class 514. Classification of the blister pack is in class 206. Applicant has not alleged that either composition, blister pack, or process claims were improperly classified. Nor has applicant alleged that the classifications set

forth are not "separate classifications." Thus, requirements 2 and 3 of MPEP§808.02 are met. For these reasons set forth above, the restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Objections

1. Claims 7 and 8 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27, 31, 32, 38, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the use of the phrase "fixed unit dosage form". It is unclear what is a "fixed dosage"? The metes and bounds of the patent protection are unascertainable. Further clarification is suggested.

Claims 19-21 are rejected in the use of the phrase "at least one part of the tablet". The term "one part of the tablet" is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how a given value can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "one part" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Claim 38 recites the limitation "wherein a separating layer" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to amend the limitation to "further comprising a separating layer".

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42).

Tari teaches omeprazole-enprostil combination useful for the treatment of peptic ulcer (pages 1744).

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. US 6,365,184, in view of Woolfe et al. US 6,387,410.

Depui teaches an oral composition comprising combination of NSAID's and proton pump inhibitor, such as omeprazole, lansoprazole, pantoprazole, or salts thereof; carriers; and

excipients (columns 5-8). The composition is useful for the treatment of gastrointestinal disorders (column 1, lines 10-18). The composition can be in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Depui does not teach combination of proton pump inhibitor and gastric antisecretory prostaglandin.

Woolfe teaches composition comprising combination of NSAID and prostaglandin, such as misoprostol (columns 1-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Depui's composition with the use of prostaglandin in view of the teachings of Woolfe, because Woolfe teaches the advantageous result in the use of misoprostol for the treatment of gastrointestinal side-effects associated with NSAID. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, and prostaglandin for the treatment of gastrointestinal disorders.

5. Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42), and Depui et al.

Akira is relied upon for the reason stated above. Although Akira teaches the combination of omeprazole-enprostil is orally administered (page 1742), Akira is silent as to the oral dosage form.

Depui teaches oral dosage form comprising omeprazole and NSAID in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Akira's composition as an oral

dosage form of Depui, because controlled/sustained release oral dosage is useful for the treatment of gastrointestinal disorders.

6. Claims 5-10, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. in view of Woolfe et al., and Shell US 5,582,837.

Depui and Woolfe are relied upon for the reasons stated above. The references are silent as to the teachings of the use of calcium channel blocker.

Shell teaches sustained release dosage form containing calcium channel blockers useful for the treatment of gastric diseases (columns 3-4). Hence, it would have been prima facie obvious for one of ordinary skill in the art to prepare composition of Depui and Woolfe with calcium channel blocker in view of the teaching of Shell, because the references teaches the advantageous result of oral formulation useful for treating gastrointestinal disorders. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, calcium channel blocker, and prostaglandin for the treatment of gastrointestinal disorders.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lerner et al., Ouali et al., and Eichman are cited as being of interest.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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